

#121

500.1004CON/RCE

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Gregor CEVC
Serial No.: 09/621,574
Filed: July 21, 2000
Examiner: Kishore, G.
For: **PREPARATION FOR THE APPLICATION OF
AGENTS IN MINI DROPLETS**

BOX: RCE
Assistant Commissioner for Patents
Washington, D.C. 20231

September 28, 2001

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the provisions of 37 C.F.R. §§ 1.97-1.99, Applicant submits herewith the following Information Disclosure Statement. Applicant respectfully requests consideration of the references listed on the attached form PTO-1449.

The undersigned attorney has recently learned that there had been an Opposition to European Patent, EP 0475160 B1 (the "EP patent") which has a specification corresponding to U.S. Patent No. 6,165,500 (the "issued U.S. patent"). The above-referenced application is a continuation of U.S. Serial No. 07/844,664 filed on April 8, 1992, now issued as the issued U.S. patent. Specifically, in the European Patent Office ("EPO"), EP 475160 B1, has been subject to an Opposition Proceeding brought on or about November 15, 1996 by ROVI GmbH (the "Opponent"). A Decision was rendered by the EPO Opposition Division on July 30, 1998 upholding the EP patent in its entirety, without any changes to the claims. An Appeal from the Decision of the EPO Opposition Division is still pending.

The claims granted in the EP 475160 B1 are different in scope from the claims pending in this application and the claims set forth in the issued U.S. patent. Nevertheless, the following information is provided so that the Examiner is able to review the arguments made by the Opponent, and the references cited during the Opposition and Appeal. For the Examiner's

convenience copies of the EP and U.S. patents are attached hereto as Exhibits A and B, respectively.

OPPOSITION OF EP 475160 B1

The EP Opponent sought revocation of the EP patent in accordance with Article 102 EPC, alleging lack of novelty and inventive step and deficient disclosure.

Three references, publications D1-D3, were cited by the Opponent, each of which is listed in the attached form PTO-1449 as references BN, BO, BP, respectively. Attached hereto as Exhibit C¹ (ref. DC on form PTO-1449) are the Opponent's arguments filed in support of the opposition request. Also attached is Exhibit D (ref. DD on form PTO-1449), the Patentee's response, wherein the Patentee requested that the Opposition be revoked as impermissible or, in the alternative, as unfounded and that a hearing be scheduled. In support of novelty, the Patentee introduced publications D4-D6, listed on form PTO 1449 as references CC, CD, CE, respectively. Exhibit E (ref. DE on form PTO-1449) hereto, is a communication to the EPO from the Patentee further supplementing the Patentee's response to the Opposition Request, filed April 21, 1997. With this document an ancillary application was filed through which the product claims were converted to utilization claims. Exhibit F (ref. DF on form PTO-1449) hereto is the Opponent's response to the Patentee's statement dated April 21, 1997. In this document, the Opponent continues to present arguments for deficient disclosure.

Exhibit G (ref. DG on form PTO-1449) dated July 30, 1998 sets forth the Decision by the EPO Opposition Division. The Opposition Division of the EPO upheld EP 475160 B1 in its entirety. More specifically, the Opposition Division held that: (i) the Opposition was permissible; (ii) the invention was sufficiently clearly disclosed to enable one skilled in the art to implement it; and (iii) the main independent claims were found to be both novel and show inventive step over the Opponent's nearest prior art of D1-D3.

APPEAL OF THE DECISION OF THE EP OPPOSITION DIVISION

The Opponent thereafter filed an Appeal from the Decision of the Opposition Division upholding the EP 475160 B1 Patent. The grounds for Appeal are set forth in Exhibit H (ref. DH

¹ Exhibits C-I hereto are attached both in German and their English translations. Each German document and its corresponding translation are marked with the same exhibit letter.

on form PTO-1449) dated December 4, 1998. In its arguments set forth in Exhibit H, the Appellant continued to argue that the specification had a deficient disclosure and the claims lacked novelty and inventive step over references D1-D3 and further argued that the claims were also not patentable over newly presented references D7-D19. Of these references, the Appellant relied upon D1, D11, D12 and D13 to allege lack of novelty of the Patentee's invention. In that regard, see specifically the Appellant's arguments at pages 24 to 30 of Exhibit H. In addition, Appellant relied upon reference D1 to allege lack of inventive step as discussed at pages 30 to 36 of Exhibit H. Furthermore, the Opponent relied upon References D14 to D19 to allege lack of novelty of the Patentee's invention as related to liquid to surfactant ratio. See, specifically, the Appellant's arguments on pages 36 to 41 of Exhibit H. Finally, Appellant relied upon references D12, D13 and D18 to challenge the accuracy of the comparative tests conducted by the Patentee during the prosecution of the EP 475160 B1. See, specifically, the Appellant's arguments at pages 41 to 45 of Exhibit H. References D12, D13 and D18 were previously made of record during the European prosecution of the EP 475160 B1 as References D4, D2 and D3 respectively, and are now listed on the accompanying form PTO-1449 as references AJ, AG and AD, respectively.

Reference D13 was made of record during the prosecution of parent application 07/844,664 by virtue of an IDS filed on July 14, 1992 providing therefor an abstract searched from Derwent World Patents Index. A complete copy of its Australian counterpart, which is in the English language, is now made of record on the accompanying PTO-1449 form as reference CB.²

Exhibit I (ref. DI on form PTO-1449) hereto is the Patentee's response to the Statement of Appeal of the Opponents. The Patentee requested that the Appellant's appeal of the decision by the Opposition Board be rejected as inadmissible or unfounded and, in the alternative that a hearing be scheduled. In support of these arguments, the Patentee provided arguments at pages 6 to 12 of Exhibit I with respect to novelty and inventive step over the cited references of D1-D3

² During the prosecution of the EP patent, the Examiner had cited reference D2, i.e., EP-A-0102324 against claim 1 to allege lack of novelty. In response, Applicant filed a revised claim 1 and submitted experimental data in which example 2 of EP-A-0102324 was duplicated except that octadecyltrimethylammonium bromide was used as the surfactant instead of cetyl trimethylammonium bromide (cetyl TAB) as specified in EP-A-0102324 which could not be obtained. Based on the results obtained by running example 2 of reference D2, Applicant argued that the resulting liposomes did not behave as the transfersomes of the invention, because, inter alia, the permeation capability of the liposomes of reference D2 was an order of magnitude smaller than that found for the transfersomes of the invention. Subsequently, Applicant reproduced experiments of example 2 of D2 by using cetyl TAB as specified in reference D2 and not octadecyltrimethylammonium bromide. More specifically, the Applicant reworked the following examples of reference D2: Experiments nos. 1, 6 and 8 of Table 1, experiments nos. 1 and 6 of Table 2, experiments nos. 1 and 10 of Table 8. Also an example with 20 mg/ml cetyl TAB was reworked. The Examiner then removed his rejection based on reference D2 and allowed the application to proceed to grant.

and D7 to D19. Additionally, the Patentee also argued at pages 8 to 11 of Exhibit I that the newly cited references D7 to D19 should be rejected as being both irrelevant and late.

COPENDING APPLICATIONS

The undersigned also respectfully directs the Examiner's attention to Applicant's copending patent applications as follows:

U.S.S.N. 09/284,683 filed June 24, 1999 entitled "Preparation for the transport of an active substance across barriers" to Cevc;

U.S.S.N. 09/555,986 filed August 17, 2000 entitled "Method for developing, testing and using associates for macromolecules and complex aggregates for improved payload and controllable de-association rates to Cevc et al.;

U.S.S.N. 09/887,493 filed June 22, 2001 entitled "Improved formulation for topical non-invasive application in vivo" to Cevc.

With respect to U.S.S.N. 09/284,683, this patent application has a corresponding German Patent Application No. P4447287.0-41 which has proceeded to grant in the German Patent Office and has issued as German Patent DE4447287C1. This patent has been opposed by the same Opponent who has opposed the corresponding EP patent filing of this application. All references cited in the Opposition to DE 4447287C1 were also cited by the opponent in the Opposition to EP 0475160B1 (which corresponds to the present application), except for references DP on form PTO-1449, which are also made of record at this time. Further, European application EPO 224837 A2, corresponds to U.S. Patent No. 4,954,345 both listed on form PTO-1449 as references CG and AA, respectively. Additionally, references cited in the above referenced copending applications and related applications pending in other foreign patent offices have also been made of record on attached form PTO-1449.

This Information Disclosure Statement is not a representation that the documents cited herein are considered most pertinent, or that a search has been undertaken or that any of the cited documents is indeed prior art. The Examiner is invited to undertake an independent search.

Pursuant to Rule 37 C.F.R. §1.97 (b), an Information Disclosure Statement shall be considered by the Patent Office if filed before the mailing date of the first Official Action on the merits. Thereafter, an Information Disclosure Statement shall be considered if it is accompanied by the requisite fees set forth in 37 C.F.R. §121.17. Since, this Information Disclosure Statement is being filed prior to the receipt of a first Official Action on the merits, no fee is required.

Finally, the Commissioner is authorized to charge any additional fee or credit, any overpayment in such fees to Deposit Account No. 50-0552.

Applicant respectfully requests that the Examiner consider and make of record the documents cited herein. Applicant further requests that a copy of the form PTO-1449, appropriately initialed by the Examiner, be returned to the Applicant in turn.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's attorney at the telephone number set forth below.

Respectfully Submitted,

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I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope with sufficient postage addressed to "Assistant Commissioner for Patents, Washington, D.C. 20231" on September 28, 2001.

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 